ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: ''USP definition'' approach or ''Dosage adjusted'' approach. The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the above data is records of generic drug applications over the past 10 years.

In the **Federal Register** of October 24, 2011 (76 FR 65733), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which, however, did not address the questions posed in 60-day notice regarding the collection of information. The comment supported the bioequivalence program but suggested a revision to the determination of bioequivalence, which relates to the substance of the scientific recommendations in the guidance document. Under FDA's good guidance practices regulations (21 CFR 10.115(f)(4)), the public may suggest at anytime that FDA revise a guidance document and under 21 CFR 10.115(g)(5), FDA will revise guidance documents in response to comments when appropriate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/solubility approach	5	5	5	10	50
Total burden hours					55

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	2	2	2	5	10
Same API/solubility approach	10	10	10	20	200
Total burden hours					210

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6391 Filed 3–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 028

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 028'' (Recognition List Number: 028), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 028'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit electronic comments concerning this document to *standards@cdrh.fda.gov.* Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 028 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 3628, Silver Spring, MD 20993, 301–796–6574.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register,** are identified in table 1 of this document.

TABLE 1—PREVIOUS PUBLICATION OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561)
October 16, 1998 (63 FR 55617)
July 12, 1999 (64 FR 37546)
November 15, 2000 (65 FR 69022)
May 7, 2001 (66 FR 23032)
January 14, 2002 (67 FR 1774)
October 2, 2002 (67 FR 61893)
April 28, 2003 (68 FR 22391)
March 8, 2004 (69 FR 10712)
June 18, 2004 (69 FR 34176)
October 4, 2004 (69 FR 59240)
May 27, 2005 (70 FR 30756)
November 8, 2005 (70 FR 67713)
March 31, 2006 (71 FR 16313)
June 23, 2006 (71 FR 36121)
November 3, 2006 (71 FR 64718)
May 21, 2007 (72 FR 28500)
September 12, 2007 (72 FR 52142)
December 19, 2007 (72 FR 71924)
September 9, 2008 (73 FR 52358)
March, 18, 2009 (74 FR 11586)
September 8, 2009 (74 FR 46203)
May 5, 2010 (75 FR 24711)
June 10, 2010 (75 FR 32943)
October 4, 2010 (75 FR 61148)
March 14, 2011 (76 FR 13631)
August 2, 2011 (76 FR 46300)

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains ''hypertext markup language (HTML)'' and ''portable document format (PDF)'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 028

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term ''Recognition List Number: 028'' to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesia	
1–15		ISO 5361–4 Second edition 1987–12–15 Tracheal tubes—Part 4: Cole type.	Contact person.
1–18		ISO 8359 Second edition 1996–12–15 Oxygen concentrators for medical use—Safety requirements.	Contact person.
1–35		ISO 5361 First edition 1999–09–15 Corrected and reprinted 1999–12–15 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Contact person.
1–36		ISO 5366–3 Second edition 2001–08–15 Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 3: Pediatric tracheostomy tubes.	Contact person.
1–44		ISO 5366–1 Fourth edition 2000–12–15 Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 1: Tubes and connectors for use in adults.	Contact person.
1–46		ISO 5367 Fourth edition 2000–06–01 Breathing tubes intended for use with anaesthetic apparatus and ventilators.	Contact person.
1–56		CGA V–7.1:1997 (Reaffirmed 2008) Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases.	Contact person.
1–57		ASTM F1101–90 (Reapproved 2003) [1] Standard Specification for Ventilators Intended for Use During Anesthesia.	Contact person.
1–58		ASTM G175–03 (Reapproved 2011) Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications.	Reaffirmation.
1–60		IEC 60601–2–12 [ISO 10651–1] Second edition 2001–10 Medical electrical equipment—Part 2–12: Particular requirements for the safety of lung ventilators—Critical care ventilators.	Contact person.
1–62		ISO 5356–1 Third edition 2004–05–15 Anaesthetic and respiratory equipment—Conical connectors: Part 1: Cones and sockets.	Contact person.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
1–69		ASTM F 1464–93 (Reapproved 2005) Standard Specification for Oxygen Concentrators for Domiciliary Use.	Contact person.
1–70		ASTM F 1246–91 (Reapproved 2005) Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits.	Contact person.
1–72		ISO 10651–5 First edition 2006–02–01 Lung ventilators for medical use—Particular requirements for basic safety and essential performance—Part 5: Gas-powered emergency resuscitators.	Contact person.
1–73		ISO 10651–4 First edition 2002–03–01 Lung ventilators—Part 4: Particular requirements for operator-powered resuscitators.	Contact person.
1–75		ISO 5362 Fourth edition 2006–06–01 Anaesthetic reservoir bags	Contact person.
1–79		ISO 26825 First edition 2008–08–15 Corrected version 2009–09–15 Anaesthetic and respiratory equipment—User-applied labels for syringes containing drugs used during anaesthesia—Colours, design and performance.	Contact person.
		B. Biocompatibility	
2–87	2–174	ISO 10993–10 Third Edition 2010–08–01 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.	Withdrawn and replaced with newer version.
2–93		ASTM F763–04 (Reapproved 2010) Standard Practice for Short-Term Screening of Implant Materials.	Reaffirmation.
2–94		ASTM F981–04 (Reapproved 2010) Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone.	Reaffirmation.
2–108		ASTM F1905–98 Standard Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity.	Withdrawn.
2–114		ASTM F1877–05 (Reapproved 2010) Standard Practice for Characterization of Particles.	Reaffirmation.
2–117		ANSI/AAMI/ISO 10993–3:2003(R)2009 Biological evaluation of medical devices—Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity.	Extent of recognition and Contact person.
2–118		ANSI/AAMI/ISO 10993–11:2006/(R)2010 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity.	Reaffirmation.
2–120		ANSI/AAMI/ISO 10993–6:2007/(R)2010 Biological evaluation of medical devices—Part 6: Tests for local effects after implantation.	Reaffirmation.
2–126		ASTM F748–06 (Reapproved 2010) Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices.	Reaffirmation.
2–134		ASTM F2065–00 (Reapproved 2010) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials.	Reaffirmation.
2–155		ASTM F2147–01 (Reapproved 2010) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens.	Reaffirmation.
2–157	2–184	USP34–NF29:2011<87> Biological Reactivity Tests, In Vitro—Direct Contact Test.	Withdrawn and replaced with newer version.
2–158	2–185	USP 34–NF29:2011 Biological Tests <87> Biological Reactivity Test, In Vitro—Elution Test.	Withdrawn and replaced with newer version.
2–159	2–186	USP 34–NF29:2011 Biological Tests <88> Biological Reactivity Tests, In Vivo, Procedure Preparation of Sample.	Withdrawn and replaced with newer version.
2–160	2–187	USP 34–NF29:2011 Biological Tests <88> Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test.	Withdrawn and replaced with newer version.
2–161	2–188	USP 34–NF29:2011 Biological Tests <88> Biological Reactivity Tests, In Vivo Classification of Plastics—Systemic Injection Test.	Withdrawn and replaced with newer version.
2–165		ANSI/AAMI/ISO 10993–14:2001 (Reapproved 2006) Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics.	Reaffirmation.
2–166	2–180	ANSI/AAMI/ISO 10993–16:2010 Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–52		ANSI/AAMI EC12:2000/(R)2010 Disposable ECG electrodes	Reaffirmation.
3–61	3–95	IEC 60601–2–27 Edition 3.0 2011–03 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Newer version with transition period.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		D. Dental/ENT	
4–76		ISO 7785–2 Second edition 1995–08–01 Dental handpieces—Part 2: Straight and geared angle handpieces.	Contact person.
4–83		ISO 11498 First edition 1997–02–15 Dental handpieces—Dental low-voltage electrical motors.	Contact person.
4–84		ISO 13294 First edition 1997–05–01 Dental handpieces—Dental air-motors.	Contact person.
4–90		ANSI S3.39 Reaffirmed by ANSI May 18, 2007 Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance).	Contact person.
4–119		ANSI/ADA Specification No. 82–1998 (R2009) Reversible/Irreversible Hydrocolloid Impression Material Systems.	Reaffirmation.
4–121		ISO 7494–2 First edition 2003–03–01 Dentistry—Dental units—Part 2: Water and air supply.	Contact person.
4–123		ANSI/ASA S3.6–2004 Specification for Audiometers	Contact person.
4–126		ISO 10477 Second edition 2004–10–01 Dentistry—Polymer-based crown and bridge materials.	Contact person.
4–134		ISO 7494–1 First edition 2004–08–15 Dentistry—Dental units—Part 1: General requirements and test methods.	Contact person.
4–136		ASTM Designation: F2504–05 Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices.	Contact person.
4–150		ANSI/ADA Specification No. 19–2003 Dental Elastometric Impression Material:2003.	Contact person.
4–154		ISO 4823 Third edition 2000–12–15 Dentistry—Elastometric impression materials.	Contact person.
4–155		ISO 4823:2000 Technical Corrigendum 1 Published 2004–07–15 Dentistry—Elastomeric impression materials.	Contact person.
4–156		ISO 4823 Third edition 2000–12–15 Amendment 1 2007–07–01 Dentistry—Elastometric impression materials.	Contact person.
4–160		ANSI S3.1–1999 (Reaffirmed by ANSI October 28, 2008) American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms.	Contact person.
4–162		ANSI S3.4–2007 American National Standard Procedure for the Computation of Loudness of Steady Sounds.	Contact person.
4–163		ANSI S3.5–1997 (R1986) Reaffirmed by ANSI May 18, 2007 American National Standard Methods for Calculation of the Speech Intelligibility Index.	Contact person.
4–164		ANSI S3.7–1995 (Reaffirmed by ANSI October 28, 2008) American National Standard Method for Coupler Calibration of Earphones.	Contact person.
4–165		ANSI S3.13–1987 Reaffirmed by ANSI June 1, 2007 American National Standard Mechanical Coupler for Measurement of Bone Vibrators.	Contact person.
4–170		ANSI S3.36–1985 Reaffirmed by ANSI on 4/27/2006 American National Standard Specification for a Manikin for Simulated in-situ Airborne Acoustic Measurements.	Contact person.
4–171		ANSI S3.37–1987 (Reaffirmed by ANSI May 18, 2007) American National Standard Preferred Earhook Nozzle Thread for Postauricular Hearing Aids.	Contact person.
4–172		ANSI S3.42–1992 Reaffirmed by ANSI May 18, 2007 American National Standard Testing Hearing Aids with a Broad-Band Noise Signal.	Contact person.
4–173		ANSI S3.44–1996 Reaffirmed by ANSI on 27 April 2006 American National Standard Determination of Occupational Noise Exposure and Estimation of Noise-Induced Hearing Impairment.	Contact person.
4–175		ANSI S3.46–1997 American National Standard Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids.	Contact person.
4–177		ANSI S12.65–2006 (Reaffirmed by ANSI March 30, 2011) American National Standard For Rating Noise with Respect to Speech Interference.	Reaffirmation.
4–179		ISO 7405 Second edition 2008–12–15 Dentistry—Evaluation of biocompatibility of medical devices used in dentistry.	Contact person.
4–180		ISO 9168 Third edition 2009–07–15 Dentistry—Hose connectors for air driven dental handpieces.	Contact person.
4–183		ANSI S3.2–2009 American National Standard Method for Measuring the Intelligibility of Speech over Communication Systems.	Contact person.
4–184		ANSI/ASA S3.25–2009 American National Standard For an Occluded Ear Simulator.	Contact person.
4–185		ANSI/ASA S3.45–2009 American National Standard Procedures for Testing Basic Vestibular Function.	Contact person.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
4–186		ANSI/ASA S12.2–2008 American National Standard Criteria for Evaluating Room Noise.	Contact person.
4–190		ANSI/ASA S3.35–2010 American National Standard Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions.	Contact person.
4–192		ANSI/ADA Specification No. 58–2010 Root Canal Files Type H (Hedstrom): 2007.	Contact person.
		E. General	
5–29		AAMI/ANSI HE74–2001 (R 2009) Human factors design process for medical devices.	Withdrawn, see 5–67.
5–39		IEC 60812 Second edition 2006–01 Analysis techniques for system reliability—Procedure for failure mode and effects analysis (FMEA).	Contact person.
5–40		ISO 14971 Second edition 2007–03–01 Medical devices—Application of risk management to medical devices.	Contact person.
5–42		ASTM D903–98 (Reapproved 2010) Standard Test Methods for Peel or Stripping Strength of Adhesive Bonds.	Reaffirmation.
5–58		IEC 60601–1–11 Edition 1.0:2010 Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	Extent of recognition and relevant guidance.
		F. General Hospital/General Plastic Surgery	
6–117		ASTM F2172–02(2011) Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers.	Reaffirmation and Contact person.
6–161		ISO 10555–1 First edition 1995–06–15 Sterile, Single-use intravascular catheters—Part 1: General requirements.	Title and Contact person.
6–164		ISO 10555–5 First edition 1996–06–15 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters.	Title and Contact person.
6–164	6–266	ISO 10555–5 First edition 1996–06–15 AMENDMENT 1 1999–01–15 Corrected and reprinted 1999–07–15 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters.	See 6–164.
6–164	6–267	ISO 10555–5:1996 TECHNICAL CORRIGENDUM 1 Published 2002–06–15 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters TECHNICAL CORRIGENDUM.	See 6–164.
6–176		ASTM D7103–06 [1] Standard Guide for Assessment of Medical Gloves	Editorial change.
6–177		ASTM E1112–00 (Reapproved 2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.	Reaffirmation.
6–198	6–254	ASTM F2100–11, Standard Specification for Performance of Materials Used in Medical Face Masks.	Withdrawn and replaced with newer version.
6–203		ASTM D6499–07, Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products.	Extent of recognition.
6–219	6–255	USP 34–NF 29<11>:2011 Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–226	6–256	USP 34–NF 29<11>:2011 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–246	6–257	USP 34–NF 29 2011 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–248	6–258	USP 34–NF 29 2011 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–249	6–259	USP 34–NF 29 2011 <861> Sutures Diameter	Withdrawn and replaced with newer version.
6–250	6–260	USP 34–NF 29 2011 <871> Sutures—Needle	Withdrawn and replaced with newer version.
6–251	6–261	USP 34–NF 29 <11>:2011 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–252	6–262	USP 34–NF 29 <11>:2011 Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
		G. In Vitro Diagnostics	
7–102	7–221	CLSI H01–A6 Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition.	Withdrawn and replaced with newer version.
7–112		CLSI H49–A Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline.	Withdrawn duplicate, see 7–162.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
7–126	7–222	CLSI M24–A2 Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standards—Second Edition.	Withdrawn and replaced with newer version Contact person.
7–128		CLSI EP14–A2 Evaluation of Matrix Effects; Approved Guideline—Second Edition.	Withdrawn duplicate, see 7–143.
7–130		CLSI H20–A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.	Withdrawn duplicate, see 7–165.
7–134		CLSI GP20–A2 Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition.	Withdrawn duplicate, see 7–166.
7–140	7–223	GP22–A3—Quality Management System: Continual Improvement; Approved Guideline—Third Edition.	Withdrawn and replaced with newer version.
7–143		CLSI EP14–A2 Evaluation of Matrix Effects; Approved Guideline—Second Edition.	Contact person, Type of standard, Processes impacted.
7–147		CLSI M22–A3 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition.	Withdrawn duplicate, see 7–178.
7–150		CLSI H43–A2 Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition.	Title, Contact person.
7–162		CLSI H49–A Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline.	Contact person, Devices affected, Processes affected, Type of standard, CFR citation and product codes.
7–165		CLSI H20–A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition.	Contact person, Devices affected, Processes affected, Type of standard, CFR citation and product codes.
7–166		CLSI GP20–A2 Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition.	Devices affected, Process affected, CFR citation and product codes.
7–169		CLSI M27–A3 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition.	Withdrawn duplicate, see 7–204.
7–172		CLSI C28–A3 Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition.	Withdrawn duplicate, see 7–224.
7–202	7–224	CLSI C28–A3c Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition.	Withdrawn and replaced with newer version.
7–178		CLSI M22–A3 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition.	Extent of recognition, CFR citation and product codes.
7–204		CLSI M27–A3 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition.	Contact person.
7–206		CLSI I/LA 20–A2 Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline—Second Edition.	Title, Contact person.
		H. Materials	
11–219	8–203	ASTM F2026–08 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Transferred.
8–101	8–204	ASTM F2118–10 Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials.	Withdrawn and replaced with newer version.
8–105	8–205	ASTM F1635–11 Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants.	Withdrawn and replaced with newer version.
8–114		ASTM F2255–05 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading.	Reaffirmation.
8–115		ASTM F2256–05 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading.	Reaffirmation.
8–116		ASTM F2258–05 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in Tension.	Reaffirmation.
8–119	8–206	ASTM F688–10 Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8–121		ASTM F2005–05 (Reapproved 2010) Standard Terminology for Nickel-Titanium Shape Memory Alloys.	Reaffirmation.
8–125		ASTM F2004–05 (Reapproved 2010) Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis.	Reaffirmation.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–126		ASTM F561–05a (Reapproved 2010) Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids.	Reaffirmation.
8–132		ASTM F1088–04a (Reapproved 2010) Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Reaffirmation and contact person.
8–135		ASTM F2392–04 (Reapproved 2010) Standard Test Method for Burst Strength of Surgical Sealants.	Reaffirmation.
8–136		ASTM F2458–05 (Reapproved 2010) Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants.	Reaffirmation.
8–172	8–207	ASTM F1926/F1926M–10 Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Granules, Fabricated Forms, and Coatings.	Withdrawn and replaced with newer version.
8–178	8–208	ASTM F648–10a Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.	Withdrawn and replaced with newer version.
8–181	8–209	ASTM F899–11 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with newer version.
8–191	8–210	ASTM F2182–11 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
8–195		ASTM F2024–10, Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings.	Extent of Recognition, devices affected, CFR citations and associated procodes and contact person.
		I. Neurology	
17–1		ANSI/AAMI NS28:1988/(R) 2010 Intracranial pressure monitoring devices.	Reaffirmation.
17–3		ISO 7197:2006 Third edition 2006–06–01 Neurosurgical implants—Sterile, single-use hydrocephalus shunts and components.	Contact person.
17–4		ASTM F 647–94 (Reapproved 2006) Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	Contact person.
17–7		ISO 7197:2006 Technical Corrigendum 1 Published:2007–07–01 Neurological implants—Sterile, single-use hydrocephalus shunts and components.	Contact person.
		J. OB–GYN/Gastroenterology	
9–21		ISO 8600–4 First edition 1997–07–01 Optics and optical instruments—Medical endoscopes and certain accessories—Part 4: Determination of maximum width of insertion portion.	Contact person.
9–37		ISO 8600–1 Second edition 2005–05–01 Optics and photonics—Medical endoscopes and endotherapy devices—Part 1: General requirements.	Contact person.
9–38		ISO 8600–3 First edition 1997–07–01 AMENDMENT 1 2003–12–01 Optics and optical instruments—Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.	Contact person.
9–39		ISO 8600–5 First edition 2005–03–15 Optics and photonics—Medical endoscopes and endotherapy devices—Part 5: Determination of optical resolution of rigid endoscopes with optics.	Contact person.
9–40		ISO 8600–6 First edition 2005–03–15 Optics and photonics—Medical endoscopes and endotherapy devices—Part 6: Vocabulary.	Contact person.
9–44		ASTM Designation: F 623–99 (Reapproved 2006) Standard Performance Specification for Foley Catheter.	Contact person.
9–49		AAMI/ANSI RD61:2006, Concentrates for hemodialysis	Withdrawn, see 9–73.
9–50		ANSI/AAMI RD52:2004/(R)2010 Dialysate for Hemodialysis	Withdrawn, see 9–70 and 9–71.
9–53		ASTM F 1992–99 (Reapproved 2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes.	Contact person.
9–55		AAMI/ANSI RD62:2006 and ANSI/AAMI RD62:2006/A1:2009, Water treatment equipment for hemodialysis applications.	Withdrawn, see 9–69.
9–61		IEC 60601–2–18 Edition 3.0 2009–08 Medical electrical equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Contact person.
9–59		AAMI/ANSI RD5:2003/(R)2008, Hemodialysis	Withdrawn, see 9–72.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		K. Ophthalmic	
10–15		ISO 9394 Second edition 1998–08–15 Ophthalmic optics—Contact lenses and contact lens care products—Determination of biocompatibility by ocular study using rabbit eyes.	Contact person.
10–24	10–67	ISO 11986 Second edition 2010–11–01 Ophthalmic optics—Contact lenses and contact lens care products—Determination of preservative uptake and release.	Withdrawn and replaced with newer version.
10–26	10–68	ISO 13212 Second edition 2011–05–15 Ophthalmic optics—Contact lens care products—Guidelines for determination of shelf-life.	Withdrawn and replaced with newer version.
10–28		ISO 14729 First edition 2001–04–15 Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.	Contact person.
10–29		ISO 14730 First edition 2000–09–15 Ophthalmic optics—Contact lens care products—Antimicrobial preservative efficacy testing and guidance on determining discard date.	Contact person.
10–33	10–69	ANSI Z80.18–2010 for Ophthalmics—Contact Lens Care Products—Vocabulary, Performance Specifications, and Test Methodology.	Withdrawn and replaced with newer version.
10–38	10–70	ISO 10943 Third edition 2011–08–15 Ophthalmic instruments—Indirect ophthalmoscopes.	Withdrawn and replaced with newer version.
10–59		ISO 11980 Second edition 2009–10–15 Ophthalmic optics—Contact lenses and contact lens care products—Guidance for clinical investigations.	Contact person.
		L. Orthopedic	
11–167	11–226	ASTM F1089–10 Standard Test Method for Corrosion of Surgical Instruments.	Withdrawn and replaced with newer version.
11–180	11–227	ASTM F366–10 Standard Specification for Fixation Pins and Wires	Withdrawn and replaced with newer version; change contact.
11–196		ASTM F1672–95 (Reapproved 2011) Standard Specification for Resurfacing Patellar Prosthesis.	Reaffirmation.
11–201	11–228	ASTM F564–10 Standard Specification and Test Methods for Metallic Bone Staples.	Withdrawn and replaced with newer version.
11–217	11–229	ASTM F2083–10 Standard Specification for Total Knee Prosthesis	Withdrawn and replaced with newer version.
11–221	11–230	ASTM F1717–10 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
11–155	11–231	ISO 7207–2 Second edition 2011–07–01 Implants for surgery—Components for partial and total knee joint prostheses—Part 2: Articulating surfaces made of metal, ceramic and plastics materials.	Withdrawn and replaced with newer version.
11–219	8–203	ASTM F2026–10 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Transferred and replaced with a newer version.
		M. Radiology	
12–52		UL 544 (1998), Standard for Medical and Dental Equipment—Ed. 4.0	Withdrawn, see 5–4 and 5–52.
12–62		UL 187 (1998), Standard for X-ray Equipment—Ed. 7.0	Withdrawn, see 5–4 and 5–52.
12–100		NEMA UD 3–2004 (R2009), Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2.	Reaffirmation.
12–105		NEMA UD 2–2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3.	Reaffirmation.
12–106		ISO 17526 First edition 2003–06–15, Optics and optical instruments—Lasers and laser-related equipment—Lifetime of lasers.	Contact person.
12–108	12–246	ISO 21254–2 First edition 2011–07–15 Lasers and laser-related equipment—Test methods for laser-induced damage threshold—Part 2: Threshold determination.	Withdrawn and replaced with newer version.
12–109	12–245	ISO 21254–1 First edition 2011–07–15 Lasers and laser-related equipment—Test methods for laser-induced damage threshold—Part 1: Definitions and general principles.	Withdrawn and replaced with newer version.
12–110		ISO 11551 Second edition 2003–12–01, Optics and optical instruments—Lasers and laser-related equipment—Test method for absorptance of optical laser components.	Contact person.
12–113		ISO 12005 Second edition 2003–04–01, Lasers and laser-related equipment—Test methods for laser beam parameters—Polarization.	Contact person.
12–115		ISO 13695 First edition 2004–06–01, Optics and photonics—Lasers and laser-related equipment—Test methods for the spectral characteristics of lasers.	Contact person.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
12–117		ISO 15367–1 First edition 2003–09–15, Lasers and laser-related equipment—Test methods for determination of the shape of a laser beam wavefront—Part 1: Terminology and fundamental aspects.	Contact person.
12–134		ISO 11146–1 First edition 2005–01–15, Lasers and laser-related equipment—Test methods for laser beam widths, divergence angles and beam propagation ratios—Part 1: Stigmatic and simple astigmatic beams.	Contact person.
12–140		AIUM RTD2–2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 2.	Title.
12–142		ISO 11146–2 First edition 2005–02–15, Lasers and laser-related equipment—Test methods for laser beam widths, divergence angles and beam propagation ratios—Part 2: General astigmatic beams.	Contact person.
12–143		ISO 15367–2 First edition 2005–03–15, Lasers and laser-related equipment—Test methods for determination of the shape of a laser beam wavefront—Part 2: Shack-Hartman sensors.	Contact person.
12–144	12–247	ISO 11990–1 First edition 2011–08–01 Lasers and laser-related equipment—Determination of laser resistance of tracheal tubes—Part 1: Tracheal tube shaft.	Withdrawn and replaced with newer version.
12–154	12–248	ISO 21254–3 First edition 2011–07–15 Lasers and laser-related equipment—Test methods for laser-induced damage threshold—Part 3: Assurance of laser power (energy) handling capabilities.	Withdrawn and replaced with newer version.
12–155		ISO 11554 Third edition 2006–05–01, Optics and photonics—Lasers and laser-related equipment—Test methods for laser beam power, energy and temporal characteristics.	Contact person.
12–156		ISO 11670:2003 Technical Corrigendum 1 Published 2004–05–15, Lasers and laser-related equipment—Test methods for laser beam parameters—Beam positional stability.	Contact person.
12–157		ISO 13694:2000 Technical Corrigendum 1 Published 2005–11–01, Optics and optical instruments—Lasers and laser-related equipment—Test methods for laser beam power (energy) density distribution.	Contact person.
12–174		ISO 13697 First edition 2006–05–15, Optics and photonics—Lasers and laser-related equipment—Test methods for specular reflectance and regular transmittance of optical laser components.	Contact person.
12–175		ISO 24013 First edition 2006–11–15, Optics and photonics—Lasers and laser-related equipment—Measurement of phase retardation of optical components for polarized laser radiation.	Contact person.
12–177	12–249	ANSI/UL 122–2007 Standard for Photographic Equipment—Ed. 5.0 ...	Withdrawn and replaced with newer version.
12–125	12–231	NEMA MS 5–2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
12–151	12–232	NEMA MS 4–2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices.	Withdrawn and replaced with newer version.
12–160	12–234	NEMA MS 12–2010, Quantification and Mapping of Geometric Distortion for Special Applications.	Withdrawn and replaced with newer version.
12–162	12–235	IEC 60731 Edition 3.0 2011–02, Amendment 1, Medical electrical equipment—Dosimeters with ionization chambers as used in radiotherapy.	Withdrawn and replaced with newer version.
12–178	12–236	IEC 60601–2–45 Edition 3.0 2011–02, Medical electrical equipment—Part 2–45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices.	Newer version with transition period.
12–191	12–237	IEC 62359 Edition 2.0 2010–10, Ultrasonics—Field characterization—Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.	Withdrawn and replaced with newer version.
12–218	12–238	NEMA PS 3.1–3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set.	Withdrawn and replaced with newer version.
		N. Software/Informatics	
13–11	13–30	CLSI AUTO3–A2 Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard, Second Edition 2009.	Withdrawn and replaced with newer version.
		O. Sterility	
14–135		AAMI/ANSI ST63:2002, Sterilization of health care products—Requirements for the development, validation and routine control of an industrial sterilization process for medical devices—Dry heat.	Withdrawn, see 14–339.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–169		ASTM F2391–05 (Reapproved 2011) Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Reaffirmation.
14–170	14–313	ASTM F2475–11 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.	Withdrawn and replaced with newer version.
14–181		ANSI/AAMI ST58:2005/(R)2010 Chemical sterilization and high-level disinfection in health care facilities.	Reaffirmation and contact person.
14–193		ANSI/AAMI/ISO 11607–1:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems.	Reaffirmation.
14–194		ANSI/AAMI/ISO 11607–2:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes.	Reaffirmation.
14–195		ANSI/AAMI/ISO 11140–1:2005(R)2010 Sterilization of health care products—Chemical indicators—Part 1: General requirements.	Reaffirmation, extent of recognition, and type of standard.
14–201		ANSI/AAMI ST77:2006/(R)2010 Containment devices for reusable medical device sterilization.	Reaffirmation and contact person.
14–214		AOAC 6.2.04:2009 Official Method 955.15, Testing Disinfectants Against Staphylococcus aureus, Use—Dilution Method.	Reaffirmation.
14–216		AOAC 6.2.06:2009 Official Method 964.02, Testing Disinfectants Against Pseudomonas aeruginosa, Use—Dilution Method.	Reaffirmation.
14–219		AOAC 6.3.06:2008 Official Method 965.12, Tuberculocidal Activity of Disinfectants.	Reaffirmation.
14–222		ANSI/AAMI/ISO 18472:2006/(R)2010 Sterilization of health care products—Biological and chemical indicators—Test equipment.	Reaffirmation, and contact person.
14–225		ANSI/AAMI/ISO 11137–2:2006 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Extent of recognition and relevant guidance.
14–227		ANSI/AAMI/ISO 11737–1:2006 Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product.	Extent of recognition and title.
14–228		ANSI/AAMI/ISO 11135–1:2007 Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–238		ANSI/AAMI/ISO 11140–5:2007, Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick-type air removal tests.	Relevant guidance.
14–261		ANSI/AAMI/ISO 17665–1:2006 Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition, relevant guidance and contact person.
14–274		ANSI/AAMI/ISO 15882:2008 Sterilization of health care products—Chemical indicators—Guidance for selection, use, and interpretation of results.	Extent of recognition.
14–276	14–314	ANSI/AAMI ST67:2011 Sterilization of health care products—Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled ''sterile''.	Withdrawn and replaced with newer version.
14–285		ANSI/AAMI/ISO 14161:2009 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Title, contact person.
14–287		ANSI/AAMI/ISO 11737–2:2009 Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.	Extent of recognition and title.
14–291		ANSI/AAMI/ISO 14937:2009 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–295		ANSI/AAMI ST81:2004/(R)2010, Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices.	Relevant guidance and contact person.
14–296		ANSI/AAMI/ISO 11138–1:2006/(R)2010 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Extent of recognition, contact person and relevant guidance.
14–297		ANSI/AAMI/ISO 11137–1:2006/(R)2010 Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition, and relevant guidance.
14–298		ANSI/AAMI/ISO 11137–3:2006/(R)2010 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects.	Extent of recognition and relevant guidance.
14–301	14–315	USP 34:2011 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–302	14–316	USP 34:2011 <71> Sterility Tests	Withdrawn and replaced with newer version.

TABLE 2—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–303	14–317	USP 34:2011 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–304	14–318	USP 34:2011 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version.
14–305	14–319	USP 34:2011 <161> Transfusion and Infusion Assemblies and Similar Medical Devices.	Withdrawn and replaced with newer version.
14–306	14–320	USP 34:2011 Biological Indicator for Steam Sterilization—Self Contained.	Withdrawn and replaced with newer version.
14–307	14–321	USP 34:2011 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–308	14–322	USP 34:2011 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–309	14–323	USP 34:2011 Biological Indicator for Steam Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–310	14–324	USP 34:2011 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
		P. Tissue Engineering	
15–7	15–27	ASTM F2315–11 Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels.	Withdrawn and replaced with newer version.
15–8		ASTM F2064–00 (Reapproved 2006) [1] Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application.	Editorial change.
15–10		ASTM F2451–05 (Reapproved 2010) Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage.	Reaffirmation.
15–12	15–28	ASTM F2103–11 Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications.	Withdrawn and replaced with newer version.
15–15	15–29	ASTM F2259–10 Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (1H NMR) Spectroscopy.	Withdrawn and replaced with newer version.
15–18	15–30	ASTM F2212–11 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs).	Withdrawn and replaced with newer version.
15–25	15–31	ASTM F2312–11 Standard Terminology Relating to Tissue Engineered Medical Products.	Withdrawn and replaced with newer version.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 028.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference Number and date
	A. Biocompatibility	
2–173	Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization	ANSI/AAMI/ISO 10993–10:2010.
2–175	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	ISO 10993–3 Second edition 2003–10–15.
2–176	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	ISO 10993–11 Second edition 2006–08–15.
2–177	Biological evaluation of medical devices—Part 6: Tests for local effects after implantation	ISO 10993–6 Second edition 2007–04–15.
2–178	Biological evaluation of medical devices—Part 12: Sample preparation and reference materials.	ISO 10993–12 Third edition 2007–11–15 Corrected version 2008–02–15.
2–179	Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.	ISO 10993–1 Fourth edition 2009–10–15.
2–181	Clinical investigation of medical devices for human subjects—Good clinical practice	ANSI/AAMI/ISO 14155:2011.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference Number and date
2–182	Clinical investigation of medical devices for human subjects—Good clinical practice	ISO 14155 Second edition 2011–02–01.
2–183	Clinical investigation of medical devices for human subjects—Good clinical practice TECHNICAL CORRIGENDUM 1.	ISO 14155: 2011 Technical Corrigendum 1 Published 2011–07–15.
	B. Cardiovascular	
3–96	Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type.	ISO 81060–1 First edition 2007–12–01.
3–97	Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	ISO 81060–2 First edition 2009–05–01.
3–98	Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type TECHNICAL CORRIGENDUM 1.	ISO 81060–2:2009 TECHNICAL CORRIGENDUM 1 Published 2011–02–15.
3–99	Evaluation of particulates associated with vascular medical devices	AAMI TIR42:2010.
3–100	Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	ANSI/AAMI/IEC 60601–2–27:2011.
	C. General	
5–68	Medical devices—Symbols to be used with medical device labels, labelling, and information to be supplied—Part 2: Symbol development, selection and validation.	ANSI/AAMI/ISO 15223–2:2010.
5–69	Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment Corrigendum 1.	IEC 60601–1–11 (First edition—2010) April 2011.
5–70	Medical devices—Application of risk management to medical devices	ANSI/AAMI/ISO 14971:2007/(R)2010.
	D. General Hospital/General Plastic Surgery	
6–263	Absorbable Surgical Suture	USP 34–NF 28 2011.
6–264	Sterile, single-use intravascular catheters—Part 1: General requirements	ISO 10555–1 First edition 1995–06–15 Amendment 1 1999–07–15.
6–265	Sterile, single-use intravascular catheters—Part 1: General requirements	ISO 10555–1 First edition 1995–06–15 AMENDMENT 2 2004–05–15.
6–268	Standard Terminology Relating to Hemostatic Forceps	ASTM F921—10 (Reapproved 2011).
6–269	Standard Terminology for Surgical Scissors—Inserted and Non-Inserted Blades	ASTM F1078—10 (Reapproved 2011).
6–270	Standard Terminology for Surgical Suture Needles	ASTM F1840–10 [1].
6–271	Standard Test Method for Bend Testing of Needles Used in Surgical Sutures	ASTM F1874—98 (Reapproved 2011).
6–272	Standard Specification for Square Drive Interconnections on Surgical Instruments	ASTM F2062—00 (Reapproved 2011).
6–273	Sharps injury protection—Requirements and test methods—Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.	ISO 23908 First edition 2011–06–11.
	E. In Vitro Diagnostics	
7–225	Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline.	CLSI GP34–A.
7–226	Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition.	CLSI GP26–A4.
7–227	Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline.	CLSI M53–A.
	F. Materials	
8–211	Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form	ISO 5834–1 Third edition 2005–06–01.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference Number and date
8–212	Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form TECHNICAL CORRIGENDUM 1.	ISO 5834–1:2005 TECHNICAL CORRIGENDUM 1 Published 2007–05–01.
8–213	Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 3: Accelerated ageing methods.	ISO 5834–3 First edition 2005–07–15.
8–214	Implants for surgery—Ultra-high molecular weight polyethylene—Part 4: Oxidation index measurement method.	ISO 5834–4 First edition 2005–05–01.
8–215	Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 5: Morphology assessment method.	ISO 5834–5 First edition 2005–06–01.
	G. Neurology	
17–9	Implants for surgery—Active implantable medical devices Part 3: Implantable neurostimulators.	ANSI/AAMI/ISO 14708–3:2008.
	H. OB–GYN/Gastroenterology	
9–69	Water for hemodialysis and related therapies	ANSI/AAMI/ISO 13959:2009.
9–70	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies.	ANSI/AAMI/ISO 23500:2011.
9–71	Quality of dialysis fluid for hemodialysis and related therapies	ANSI/AAMI/ISO 11663:2009.
9–72	Medical electrical equipment, Part 2–16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment.	ANSI/AAMI/IEC 60601–2–16:2008.
9–73	Concentrates for haemodialysis and related therapies	ANSI/AAMI/ISO 13958:2009.
9–74	Concentrates for haemodialysis and related therapies	ISO 13958 Second edition 2009–4–15.
	I. Ophthalmic	
10–71	Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.	ISO 14729 First edition 2001–04–15 AMENDMENT 1 2010–10–01.
10–72	Ophthalmic instruments—Fundamental requirements and test methods—Part 1: General requirements applicable to all ophthalmic instruments.	ISO 15004–1 First edition 200–606–01.
	J. Orthopedic	
11–232	Implants for surgery—Components for partial and total knee joint prostheses—Part 1: Classification, definitions and designation of dimensions.	ISO 7207–1 Third edition 2007–02–01.
11–233	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.	ASTM F384—06 (Reapproved 2011).
11–234	Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses.	ASTM F732—00 (Reapproved 2011).
	K. Radiology	
12–233	Lasers and laser-related equipment—Test methods for laser beam parameters—Beam positional stability.	ISO 11670 Second edition 2003–04–01.
12–239	SAFETY OF LASER PRODUCTS—Part 1: Equipment classification and requirements, INTERPRETATION SHEET 1.	IEC 60825–1 (Second edition—2007) I–SH 01 December 2009.
12–240	SAFETY OF LASER PRODUCTS—Part 1: Equipment classification and requirements, INTERPRETATION SHEET 2.	IEC 60825–1 (2007), second edition/I–SH 02 January 2011.
12–241	Medical electrical equipment—Safety of radiotherapy record and verify systems	IEC 62274 First edition 2005–05.
12–242	Medical electrical equipment—Part 2–57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.	IEC 60601–2–57 Edition 1.0 2011–01.
12–243	Optics and optical instruments—Lasers and laser-related equipment—Test methods for laser beam power [energy] density distribution.	ISO 13694, First edition 2000–04–01.
12–244	Ultrasonics—Field characterization—Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields CORRIGENDUM 1.	IEC 62359 (Second edition—2010).

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference Number and date
	L. Sterility	
14–325	Sterilization of health care products—Vocabulary	ISO/TS 11139 Second edition 2006–01–15.
14–326	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products.	ISO 11737–1 Second edition 2006–04–01.
14–327	Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.	ISO 11737–2 Second edition 2009–11–15.
14–328	Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	ISO 11137–1 First edition 2006–04–15.
14–329	Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose	ISO 11137–2 First edition 2006–04–15.
14–330	Sterilization of health careproducts—Radiation—Part 3: Guidance on dosimetric aspects	ISO 11137–3 First edition 2006–04–15.
14–331	Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	ISO 11135–1 First edition 2007–05–01.
14–332	Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick-type air removal tests.	ISO 11140–5 Second edition 2007–03–15.
14–333	Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 17665–1 First edition 2006–08–15.
14–334	Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results.	ISO 15882 Second edition 2008–09–01.
14–335	Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals	ISO 10993–7 Second edition 2008–10–15.
14–336	Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	ISO 14161 Second edition 2009–09–15.
14–337	Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.	ISO 14937 Second edition 2009–10–15.
14–338	Sterilization of health care products—Biological indicators—Part 1: General requirements	ISO 11138–1 Second edition 2006–07–01.
14–339	Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ANSI/AAMI/ISO 20857:2010.
14–340	Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 20857 First edition 2010–08–15.
14–341	Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities	ASTM E2303—11.
14–342	Standard Practice for Dosimetry in Radiation Processing	ASTM E2628—09 [1].
14–343	Standard Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing.	ASTM E2701—09.
14–344	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	ASTM F2825—10 [1].
14–345	Standard guide for selection and calibration of dosimetry systems for radiation processing	ISO/ASTM 51261 First edition 2002–03–15.
14–346	Standard Practice for Use of a Polymethylmethacrylate Dosimetry System	ISO/ASTM 51276 Second edition 2002–12–15.
14–347	Standard Practice for Dosimetry in Gamma Irradiation Facilities for Radiation Processing	ISO/ASTM 51702 Second edition 2004–08–15.
14–348	Aseptic processing of health care products—Part 2: Filtration	ANSI/AAMI/ISO 13408–2:2003.
14–349	Aseptic processing of health care products—Part 3: Lyophilization	ANSI/AAMI/ISO 13408–3:2006.
14–350	Aseptic processing of health care products—Part 4: Clean-in-place technologies	ANSI/AAMI/ISO 13408–4:2005.
14–351	Aseptic processing of health care products—Part 5: Sterilization in place	ANSI/AAMI/ISO 13408–5:2006.
14–352	Aseptic processing of health care products—Part 6: Isolator systems	ANSI/AAMI/ISO 13408–6:2005.
14–353	Sterilization of health care products—Chemical indicators—Part 1: General requirements	ISO 11140–1 Second edition 2005–07–15.
14–354	Sterilization of health care products—Biological and chemical indicators—Test equipment	ISO 18472 First edition 2006–06–01.
14–355	Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems.	ISO 11607–1 First edition 2006–04–15.
14–356	Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes.	ISO 11607–2 First edition 2006–04–15.
14–357	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products.	ISO 11737–1:2006 TECHNICAL CORRIGENDUM 1 Published 2007–05–15.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference Number and date
	M. Tissue Engineering	
15–32	Standard Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy.	ASTM F2260–03 (Reapproved 2008).
15–33	Standard Test Method for Determining the Molar Mass of Chitosan and Chitosan Salts by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	ASTM F2602–08 [1].
15–34	Standard Test Method for Determining the Molar Mass of Sodium Alginate by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	ASTM F2605–08 [1].
15–35	Standard Guide for Characterization of Hydrogels used in Regenerative Medicine	ASTM F2900–11.
15–36	Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products (TEMPs).	ASTM F2383–11.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard; (2) any reference number and date; (3) name and address of the national or international standards development organization; (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply; and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 028'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 028. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: March 12, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6389 Filed 3–15–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–M–0735, FDA–2011–M–0736, FDA–2011–M–0737, FDA–2011–M–0746, FDA–2011–M–0786, FDA–2011–M–0791, FDA–2011–M–0792, FDA–2011–M–0796, FDA–2011–M–0832, FDA–2011–M–0837, FDA–2011–M–0848, FDA–2011–M–0865, FDA–2011–M–0866, FDA–2011–M–0910, and FDA–2011–M–0917]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.